

Appln No. 10/589,220
Amdt date July 15, 2011
Reply to Office action of April 15, 2011

REMARKS/ARGUMENTS

Claims 1-24, 37, and 38 remain in the present application, of which claims 1 and 37 are independent. Claims 25-36 have been cancelled herein without prejudice. New claims 37 and 38 have been added herein, and find full support in the original specification and claims, for example at original claim 1, and page 19, lines 13-16, page 28, line 15 through page 30, middle of the page, and page 38, line 10 through page 39, line 4 of the specification. No new matter has been added. Applicant requests reconsideration and allowance of claims 1-24, and consideration and allowance of claims 37 and 38.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 1-2, 4-12, 14-15 and 19-20 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, the Examiner alleges that Claims 1-2, 4-12, 14-15 and 19-20 contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicant submits that the Examiner's rejection of Claims 1-2, 4-12, 14-15 and 19-20 on this ground is improper.

The written description requirement is designed to ensure that the inventors had possession of the specific subject matter claimed, as of the filing date of the application. The CCPA articulated the function of this requirement in *In re Edwards*, stating:

[The f]unction of [the] description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; to comply with the description requirement, it is not necessary that the application describe the claimed invention in *ipsis verbis*; all that is required is that it reasonably convey to persons skilled in the art that, as of the filing date thereof, the inventor had possession of the subject matter later claimed by him...

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In re Edwards, 568 F.2d at 1351-52, 196 U.S.P.Q. at 467 (citations omitted). The Examiner bears the burden of establishing a *prima facie* case of noncompliance with the written description requirement by presenting evidence or reasons why person skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.

The Examiner appears to allege that the rejected claims are not supported by the specification as originally filed, and accordingly are too broad. However, it is unclear as to what relevance the Examiner's statements regarding *In re Ruschig* have with respect to the allegation that the claims are too broad. The Examiner's statements appear to be directed to a factual situation where the issue is whether a claim directed to a particular compound is supported by a specification that discloses a generic class of compounds to which the particular compound belongs, but does not describe the particular compound specifically.

Applicant disagrees with the Examiner's contention that "the claims are devoid of any structural elements that correlate to the function which is to be achieved with the claimed compound". Applicant also disagrees with the Examiner's contention that the instant claims generically claim the invention by function alone, indicating only what the agent does, rather than what it is.

Claim 1 of the present application recites: [a] compound of the formula:



wherein

each R is a group comprising at least one carbon, nitrogen, phosphorus or sulfur atom and G is joined to R through said carbon, nitrogen, phosphorus or sulfur atom;

G is silicon or boron;

m is 2 to 5 and n is 1 to 3 with m + n = 3 to 6 when G is silicon;

m is 1 to 3 and n is 1 to 3 with m + n = 3 to 4 when G is boron;

and wherein the compound further comprises one or more counterions when the above formula is charged; and wherein at least one F is ^{18}F .

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Contrary to the Examiner's characterization that the claims describe the invention by function only, the formula $(F)_m G (R)_n$ recited in Claim 1 represents a definition of the claimed subject matter in terms of formulae and chemical structural features of the compounds.

Moreover, the particular elected species (i.e., an aryl group) provides further chemical structural features of the claimed compounds, and Applicant disagrees with the Office's allegation that the expression "aryl moiety capable of bonding to a biomolecule" is devoid of any structural elements that correlate to the function which is to be achieved with the claimed compound. The expression "aryl moiety capable of bonding to a biomolecule" does not describe the chemical moiety by function alone since the term "aryl" is a chemical structural definition of the chemical moiety. Furthermore, there is a structure-function correlation known to those of ordinary skill in the art since the chemical structural components of the aryl moiety capable of bonding to a biomolecule, for example, linking or reactive groups, are well known in the art. As described on page 15 of the present application:

Groups which facilitate subsequent addition of a biomolecule are well known in the art and may include moieties which readily form a bond to a selected biomolecule, a variety of such groups being known in the art. These include thiol and amine reactive groups and other such groups which may be useful for joining a compound of this invention to functionalities on biomolecules including hydroxide, carboxylic acid, amine, sulfhydryl groups, etc. Contemplated herein, is the joining of a compound of this invention to a biomolecule through bonds other than covalent bonds. Thus, groups, which provide for ionic, hydrophobic and other non-covalent to a biomolecule are contemplated.

The synthetic organic chemistry for bonding aryl moieties to biomolecules is well within the knowledge of those of ordinary skill in the art. That this structure-function correlation is known to those of ordinary skill in the art is further supported by the description of linking groups or reactive groups for bonding with a biomolecule found in the description of symbols X, Y, and R on pages 18, 19, 21-24 and 26-28 of the present application.

Applicant submits that the present application reasonably conveys to persons skilled in the art that, as of the filing date, the inventors had possession of the claimed subject matter. The

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present application provides a precise definition by structure and formula of the claimed subject matter sufficient to distinguish it from other materials. The claimed compounds of the formula $(F)_m G (R)_n$ are defined in terms of formula and chemical structure. The present application also provides description of the symbols m, G, R and n and description of F as described on pages 4, 11-13, 15, 18, 19 and 21-28.

Applicant submits that the present application provides a precise definition of the expression “aryl moiety capable of bonding to a biomolecule”. The present application provides description of “aryl”, for example, on pages 11, 15, 19, 22, 24, 25, 27 and 28. Description of chemical structural moieties capable of bonding to a biomolecule is provided by the present application, for example, on pages 15, 18, 19, 21-24 and 26-28. Description of “biomolecule” is provided, for example, on pages 11-14. In addition, the present application provides description of illustrative synthetic routes for aryl moiety bonding to a biomolecule, for example, on pages 28-30. The present application also provides illustrative working examples of aryl moiety bonding to a biomolecule, for example, in Examples 2, 4, 6 and 8-11.

That the present application reasonably conveys to persons skilled in the art that the inventors had possession of the claimed subject matter is also supported by the fact that the present application provides description of methods of producing the claimed compounds. Methods of producing the claimed compounds are described, for example, on pages 4 and 5 of the present application. The present application provides description of processes for obtaining ^{18}F , for example, on page 6. ^{18}F -containing fluorinating agents are described, for example, on page 7. Processes for fluorination are described, for example, on pages 8-10 and 14-27. In addition, illustrative synthetic routes for preparing compounds of the claimed invention are described, for example, on pages 28-33. The present application also provides illustrative embodiments of the claimed invention in multiple working Examples on pages 33-48.

Applicant submits that the claims provide a precise definition of the structure and

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formula which describes the claimed subject matter in a manner sufficient to distinguish it from other materials. Furthermore, the present application describes the claimed invention in a manner which reasonably conveys to persons skilled in the art that, as of the filing date, the inventors had possession of the claimed subject matter. Applicant respectfully requests that the written description rejection under 35 U.S.C. § 112 be withdrawn.

New Claims 37 and 38

New independent claim 37 and dependent claim 38, which depends from claim 37, have been added herein. Applicant submits that new claims 37 and 38 also provide a precise definition of the structure and formula which describe the claimed subject in a manner sufficient to distinguish it from other materials. Examples of the particular aryl groups recited in claim 38 can be found at pages 29, 30, and 38 of the specification. As discussed at the bottom of page 28 of the specification, precursor compounds including the aryl groups recited in claim 38 may be easily fluorinated with ¹⁸F as described in the specification. Accordingly, Applicant requests consideration and allowance of new claims 37 and 38.

Concluding Remarks

In view of the foregoing amendments and remarks, Applicants earnestly solicit a timely issuance of a Notice of Allowance with claims 1-24, 37, and 38. If there are any remaining issues that can be addressed over the telephone, the Examiner is cordially invited to call Applicants' attorney at the number listed below.

Respectfully submitted,
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